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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,872	11/12/1999	KENT C. COCHRUM	44041.010400	9965
26191	7590	05/18/2005	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			MARX, IRENE	
		ART UNIT	PAPER NUMBER	1651

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/438,872	COCHRUM ET AL.
	Examiner	Art Unit
	Irene Marx	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 April 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 37-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 37-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 4/11/05 has been entered.

Claims 37-46 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40 and 41 are vague and indefinite in the recitation of trademarks to denote the dextrans intended to be used in the process, such as HP 15 and HP 20. These products are not defined with any specificity in the as-filed invention. See, page 15, for example. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name. "To describe physical or other properties of material by mere use of **trademark** is objectionable since it has tendency to make trademark descriptive of product rather than leaving trademark to serve its traditional purpose which is to identify product's source of origin". The issue involved the use of the Trademark **Hypalon** in the claims which Appellants have argued to be within the guidelines of M.P.E.P. 608.01 (v) if the meaning of the trademark is well known and satisfactorily defined in the literature. Copies of articles were submitted. No rejection was made based on first paragraph of 35 USC 112 which was correct but the rejection was on second paragraph which was considered to be correct by the board. "A patent applicant has an obligation that is imposed by 35 USC 112, second paragraph, to employ claim terminology which is definitive of what the public is not free to use, and use of a trademark in

the manner employed by appellant has resulted in claims which fail to meet this obligation in our opinion.: see *Ex parte Simpson and Roberts* 218 USPQ 1020.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-39, 42-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation “wound dressing comprising a gauze matrix having a coating of **cross-linked polysaccharide beads**” or a coating wherein the beads are **starch, alginate or cellulose**, does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of “wound dressing comprising a gauze matrix having a coating of cross-linked polysaccharide beads”. There is only one exemplified “wound dressing comprising a gauze matrix having a coating of cross-linked polysaccharide beads”, wherein the wound dressing comprising cross-linked dextran beads. This is not sufficient support for the new genus “wound dressing comprising a gauze matrix having a coating of cross-linked polysaccharide beads”, i.e. for beads other than dextran, such as beads of “ starch, alginate or cellulose”. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of “wound dressing comprising a gauze matrix having a coating of cross-linked polysaccharide beads”, wherein the beads are starch, alginate or cellulose, is considered to be the insertion of new matter for the above reasons.

Moreover, the recitations in claims 41-42 are deemed to lack proper basis or support in the written disclosure, since these materials are not disclosed in the environment of a "dry, removable wound dressing wherein the gauze matrix has a "coating of cross-linked polysaccharide beads". The compositions encompassing HP 15 or HP 20 are used in this context. In addition, the molecular weight exclusion limits recited in claims 43-44 are based exclusively on two proprietary products, HP 15 or HP 20, the source and availability of which cannot be determined .

Please see *Gentry Gallery v. Berkline* 45 U.S.P.Q.2d 1498 for a discussion related to broadening the claimed invention without support in the as-filed specification. Please see *PurduePharma v. Faulding* 56 U.S.P.Q.2d 1481 for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

In addition, no basis or support is found in the instant specification for the recitation in claim 46 of mixtures of the recited pharmaceutical agents.

Therefore, this material constitutes new matter and should be deleted.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 72-84 of copending Application No. 10/334864.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the applications is directed to substantially the same subject matter, i.e., in the instant claims, the invention in claimed in terms of a gauze matrix coated with a cross linked polysaccharide, which can be dextran, starch alginate or cellulose, while in the copending case it is claimed in terms of a coating which is covalently linked to a cellulose bandage, which can be a cotton gauze. A coating may well be covalently linked to a substrate, in this case a gauze or cellulose bandage.

Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37 and 39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Eagles *et al.* (U.S. Patent No. 5,840,777).

The claims are directed to a gauze coated with a polysaccharide such as alginate. Eagles *et al.* discloses a gauze coated with a polysaccharide such as alginate (See, e.g., Example 3. It is noted that the alginate is crosslinked. It is presumed that beads are present at least to some extent.

Claims 37-39, 44 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Patel. (U.S. Patent No. 5,470,576).

The claims are directed to a gauze coated with a polysaccharide such as alginate. Patel discloses a gauze coated with a polysaccharide such as alginate (See, e.g., Example 3. It is noted that the alginate is crosslinked. It is presumed that beads are present at least to some extent. The adhesive is disclosed at col. 7, lines 27-30. The pharmaceutical agents are disclosed at col. 6, lines 59-63.

Claims 37-39, 44 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Johnson & Johnson (U.K. Patent No. 629,419).

The claims are directed to a gauze coated with a polysaccharide such as alginate. Johnson & Johnson discloses a gauze coated with a polysaccharide such as alginate. See, e.g., page 2, col. 1, lines 163 and col. 2, lines 92-112. It is noted that the alginate is crosslinked at least to some extent. It is presumed that beads are present at least to some extent. The adhesive is disclosed at page 3, first paragraph.

Claims 37-44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson & Johnson (U.K. Patent No. 629,419) or Patel. (U.S. Patent No. 5,470,576) taken with G.B. 1454055 and Smith (U.S. Patent No. 3,671,280)

The claims are directed to a gauze coated with a cross-linked polysaccharide such as alginate, dextran, starch or cellulose.

Each of Johnson & Johnson and Patel discloses a gauze coated with a polysaccharide such as alginate (See, e.g., Johnson & Johnson, page 2, col. 1, lines 163 and col. 2, lines 92-112 or Patel, Example 3). It is noted that the alginate is crosslinked. The adhesive is disclosed at Johnson & Johnson, page 3, first paragraph or Patel col. 7, lines 27-30. The pharmaceutical agents are disclosed at Patel, col. 6, lines 59-63.

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The references may differ from the claimed invention in that the gauze is not explicitly coated with cross-linked dextran beads. However, G.B. 1454055 discloses a gauze wound dressing comprising dextran-epichlorohydrin polymer particles or beads wherein in at least one embodiment the hydrophilic polymer is chosen such that its pores will have a molecular weight exclusion limit of at least 270,000. (See, e.g., page 2, lines 3-9). Disinfectants may be added to the carrier (page 6, line 36).

In addition, Smith teaches a composition composed of a gauze matrix coated with a composition comprising high molecular weight dextran. See, e.g., Examples 7-9.

The references also differ from the claimed invention in the use of HP 15 or 20. The recited HP 15 and HP 20 appear to be dextran-epichlorohydrin polymer particles or beads, as used in the British patent. However, the molecular weight exclusion range of these products could not be assessed, inasmuch as these products do not appear to be commercially available. In any event, the molecular weight exclusion limit of at least 270,000 discussed in the British patent appears to be substantially the same as claimed. However, even if it is not, the selection of a cross-linked dextran polymer coating for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such selection is at the essence of biotechnical engineering.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in substituting cross-linked dextran for alginate because both of these polysaccharide polymers have suitable properties for use in gauze coated bandages, such as being hemostatic and preventing adhesion.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the gauze coated with a cross-linked polysaccharide as taught by Johnson & Johnson or Patel by substituting therefor a cross-linked polysaccharide such as dextran as taught by G.B. 1454055 and Smith for the expected benefit of obtaining a dry, removable wound dressing which is more pliable and more easily removable and which has the hemostatic properties provided by a dressing comprising a cross-linked dextran polymer as a coating.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson & Johnson (U.K. Patent No. 629,419) or Patel (U.S. Patent No. 5,470,576) taken with G.B. 1454055 and Smith (U.S. Patent No. 3,671,280) as applied to claims 37-44 and 46 above, and further in view of Larson, Eloy *et al.* and Nangia *et al.* (US 5,196,190).

The invention as discussed supra differs from the claimed invention in the addition of collagen, fibrinogen or thrombin to the wound dressing.

However, collagen, fibrinogen or thrombin are known hemostatic agents as described by Larson and Eloy *et al.* In addition, Nangia teaches that cross-linked dextran has hemostatic properties (col. 10, line 50).

The addition of thrombin or fibrinogen or collagen to the wound dressings of Johnson & Johnson or Patel as modified by G.B. 1,454,055 would have been obvious when the references were taken with the teachings of Larson or Eloy *et al.* and '190 because cross-linked dextran, thrombin, fibrinogen and collagen are known hemostatic agents and have been used in the past as such in the treatment of wounds in conjunction with wound dressings.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651